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**510(K) K081547**
Bio-Med USA Inc

# Summary of safety and effectiveness

July 29 2008

In accordance with Section 513(1) of the SMDA as defined in 21CFR part 807.3, This summary is submitted to obtain Premarket 510(K) notification

Manufacturer
**Sung Shim Medical Co., Ltd.**
156-8, Dodang, Wonmi-ku, Bucheon, Kyungki-do, Korea zip 420-805,

1. Contact person.
   Mr. Young Y Chi.
   Bio-Med USA Inc.
   111 Ellison Street,
   Paterson, NJ 07505. U.S.A.
   Tel: 973 870 2361
   Fax: 201 934 6030
   E mail: biomedusa@msn.com

2. Name of Medical Device
   Trade name : "Bio-Med ® Soft" Insulin Syringe
   Classification name : Piston Syringe
   Common or usual name: Insulin Syringe
   Regulation : 880.5860
   Class : II
   Product code : FMF/FMI

3. Substantial Equivalence (Identification of legally Marketed Device)
   The "Bio-Med® Soft" Insulin Syringe are substantially equivalent in Intended use, Design, Function, Performing and all Used Material to other several Insulin Syringe previously cleared by the 510(K) process as listed below

| 510(K) | Brand | Company |
|---|---|---|
| K024112, K980580 | Ultra Fine II | Becton Dickinson |
| K991758 , K851090 | Monoject | Kendall Monoject |
| K992802 | Terumo Insulin | Terumo Inc. |
| K070917 | Feel-Ject Insulin | Feel-Tech |
| K063348 | Top Fine Insulin Syringe, Dae Jin | |

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4.Device Description

"Bio-Med® Soft" Insulin syringe are sterile, single use, disposable hypodermic syringes with a permanently affixed lumen needle to the tip of syringe. The syringe consists of a barrel, a plunger rod with Synthetic Rubber Gasket, and an orange colored end-cap over the needle to preserve sterility of the fluid path.

In addition the "Bio-Med® Soft" Insulin syringe are non-toxic and pyrogenic free "Bio-Med® Soft" Insulin syringe are available 1.0cc (100units), 0.5cc (50units), 0.3cc (30 units) with 29G, 30G, 31G, needle thickness, ½:", 5/16" needle length, and meet the following standard:

ISO 7864 Sterile, Hypodermic Needles for single use

ISO 8537: 1991/Amendment 1: 2000 Sterile, Single use Syringe with/without needle For insulin

5 Device Intended use

Bio-Med® Soft Insulin Syringe is single use, sterile, intended use for the subcutaneous injection of U 100 Insulin only.

6 Summary of Technological characteristics.

"Bio-Med ®Soft" Insulin Syringe are the same function, performing as those currently on market in permanently attached hypodermic, lumen needle to the tip of syringe, and there are no significant difference in technological characteristic between the "Bio-Med® Soft" Insulin Syringe and cited predicate device, accordingly, no any new issues of safety or effectiveness raised. This device operates on principles of piston syringe.

7 Packaging and Labeling

The "Bio-Med® Soft" Insulin syringe is sterilized, and packed in blister individually, and one hundred blister packs are packed in a Chipboard box, and also provided 10 sterilize syringe in a poly bag, 10 poly bag in a Chipboard box. Each blister pack, poly bag and Chipboard box are labeled with the contents and appropriate information per the FDA's quality systems regulation and labeling requirement (21 CFR part 801)

- Each size Blister label sample attached
- Each size Inner box drawing sample attached
- 10pcs poly bag drawing attached

8. Biocompatibility certify

Bio-Med® soft Insulin Syringe use the exact same raw material, which has been previously tested as Medical grade and accepted Biocompatibility, and is also manufactured with same process as already cleared Predicate Device K070917 Feel Ject Insulin Syringe.

Finished needle attached Insulin Syringe by FDA guidance Blue Book Memo G95-1, use of ISO 10993 Biological Evaluation of Medical Device part ,4,5,10,11,12
Body contact Classification: Externally Communicating Device Blood path indirect, limited contact less than 24 hrs.

**The blood contacting materials were found to be Biocompatible.**

## Conclusion

The "Bio-Med® Soft" Insulin Syringe submitted in this Pre-market notification is substantially equivalent to the Terumo Insulin Syringe K 822083, K992802, Becton Dickinson Ultra Fine II K955235, Feel-Ject Insulin Syringe K070917 in respect to intended use, design, used material, producing process, Technology / Principle of Operation and Performance.
Differences between the devices do not raise any new issues of safety or effectiveness

End of Summary

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Young Chi
President
Bio-Med USA Incorporated
111 Ellison Street
Paterson, New Jersey 07505

Re: K081547
Trade/Device Name: Bio-Med® Soft Insulin Syringe 1cc, 0.5cc, 0.3cc Needle Gauge, 29G, 30G, 31G, length ½", 5/16"
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: August 20, 2008
Received: August 26, 2008

Dear Mr. Chi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Samuel Lin for

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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# Indications for use

| | |
|---|---|
| 510(K) number | : K081547 |
| Device Name | : Bio-Med ®Soft Insulin Syringe<br>1cc, 0.5cc, 0.3cc needle Gauze, 29G, 30G, 31G,<br>length ½", 5/16" |
| Indications for use | : Single use, sterile, intended use for the subcutaneous injection of U-100 Insulin only. |

Prescription Use_____ and/or Over-The-Counter Use__X__
( Part 21 CFR 801 Subpart D) (21CFR 801 subpart C)

(PLEASE DON NOT WRITE BELOW THIS LINE-CONTINUED ON ANOTHER PAGES IF NEEDLED)

Concurrence of CDRH, Office of Device Evaluation ( ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K081547